IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Stuart A. Lipton
Serial No. : 08/346,910
Filed : November 30, 1994
Title : PROTEIN 68075 AND ITS USE FOR REGENERATING NERVE CELL PROCESSES

Art Unit : 1647
Examiner : Gucker, S.

Commissioner for Patents
Washington, D.C. 20231

REVISED BRIEF ON APPEAL

(1) Real Party in Interest

The inventor, Stuart A. Lipton, is the owner of this patent application and the real party in interest in this appeal.

(2) Related Appeals and Interferences

There are no related appeals or interferences.

(3) Status of Claims

Claims 8, 11, and 12 are allowed.

This appeal is taken from the final rejection of claim 14.

No other claims are pending in this application.

(4) Status of Amendments

The claims under consideration in the final rejection mailed November 21, 2000 have not been amended.

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I hereby certify under 37 CFR §1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated below and is addressed to the Commissioner for Patents, Washington, D.C. 20231.

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(5) Summary of Invention

Applicant has discovered clones from a human gene involved in neuronal differentiation. The gene is now known as Mef2C, although that name was assigned to it by others after Applicant's discovery. The clones are discussed at page 8 of the specification ad particularly at page 8, line 29 through page 9 line 5.

(6) Issues

Does the specification as filed demonstrate to those skilled in the field that the applicant was in possession of the invention featured in claim 14, as required by 35 U.S.C. §112 ¶1?

Does claim 14 constitute new matter with respect to the specification as filed, in violation of 35 U.S.C. §132?

Does the specification as filed enable those skilled in the field to practice the invention featured in claim 14, as required by 35 U.S.C. §112 ¶1?

(7) Grouping of Claims

Only one claim is at issue in this appeal, claim 14.

(8) Argument

Claim 14 stands rejected under 35 U.S.C. §112 ¶1 on the finding that the specification as filed lacks a written description of the invention of claim 14 and the specification as filed fails to enable those skilled in the field at the time of the invention to make, use and practice the invention of claim 14.

A. The specification as filed demonstrates that the Applicant was in possession of the invention featured in claim 14.

1. The written description standard.

The statutory requirement to provide a written description the invention is embodied in 35 U.S.C. §112 ¶1, "The specification shall contain a written description of the invention...." The courts have analyzed this requirement as requiring a description of the invention that one

skilled in the art can conclude that "the inventor invented the claimed subject matter". Stated another way, the specification must support the conclusion that the inventor had possession of the claimed invention. *Regents of California v. Eli Lilly & Co.*, 119F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The US PTO has provided guidelines for application of the written description requirement during examination (66 Fed. Reg.1099 et seq., January 5, 2001). These guidelines explain that the policy objectives of the written description requirement are (66 Fed.Reg. 1104-5):

- clearly convey to the public what was invented:
- put the public in possession of what the applicant claims as the invention; and
- prevent an applicant fro claiming subject matter that was not described in the specification as filed.

The USPTO carries the initial burden of establishing why a person skilled in the art would not recognize that the specification contains a written description of the claimed subject matter, and there is a strong presumption that an adequate written description of the claimed invention is present when the application is filed (66 Fed. Reg. 1099).

An applicant may meet the written description requirement by showing actual reduction to practice (see the Interim Written Description Guidelines, 64 Fed. Reg. 71427 (December 21, 1999). Actual reduction to practice can be established by constructing an embodiment or performing a process that meets all of the limitations of the claim, providd the invention would work for its intended purpose. (Id)

So the PTO guidelines set out the task at hand. To determine the correspondence between what the applicant has described as the essential identifying characteristic features of the invention, i.e., what applicant has demonstrated possession of, and what applicant has claimed. (Id)

2. The specification as filed

Let's review what the specification shows.

There is no dispute that Applicant isolated and deposited four DNA clones deposited with the American Type Culture Collection under accession numbers: ATCC 97525; ATCC 68075: and ATCC 75949. There is also no question that

Applicant demonstrated the utility of those clones as probes. At pages 7-8, the specification details the procedure for obtaining the 500bp clone "TR1" (deposit 68075). At page 8, lines 28 et seq., the specification details the use of that clone as a probe.

Rescreening of the brain library with the 500bp clone [TR1] identified two two kilobase clones (clones TR2A and TR2B) and three three[-]kilobase clones (clones TR3A, TR3B, and TR3C) clones to which the 500bp clone hybridized.

The above clone [deposit 68075] ... can be used to identify other candidate clones to insure that a full length ... clone is obtained."

Further along in the specification, Applicants are more specific about the use of probes (4:13-20).

"the probe is a portion of at least 15-20 contiguous bases of the nucleic acid encoding human 68075 [now called MEF2C]. This probe nucleic acid is used under standard stringent hybridization conditions to identify nucleic acid homologous to that encoding the human 68075. ***Not all such homologous sequences will encode a 68075 protein. but those which do can be identified bv standard procedures."***

It is hard to imagine how Applicants could have been more explicit that the clone could be and was used as a probe.

3. Claim 14

We now compare that reduction to practice with claim 14 which provides,

14. An isolated fragment of nucleic acid comprising at least 20 contiguous bases of clone ATCC 97525, wherein said nucleic acid is able to selectively hybridize to nucleic acid encoding human MEF2C.

The above-quoted segments of the specification demonstrate a reduction to practice of every element of claim 14.

4. The basis for the rejection

What then is the basis for the rejection? The Examiner complains,

"[A] fair reading of the specification indicates that the Applicant does not have either verbatim or conceptual support for the recited limitation of a nucleic acid that would ***selectively*** *hybridize to nucleic acid encoding human MEF2C."*

That conclusion rests on the language highlighted in the above quotation, to the effect that not **all** sequences that hybridize to the probe will encode the desired MEF2C protein. The Examiner concludes that the specification discloses that probes of at least 20 bases **cannot selectively** hybridize to nucleic acid encoding human MEF2C because not all such sequences which the probe will hybridize to will actually encode human MEF2C. In other words, according to the Examiner, the **hybridization is not selective because other standard procedures for identification must be performed**. Therefore, the Examiner concludes, a probe that meets the limitation of selective hybridization to an encoding nucleic acid sequence has not been taught by the disclosure.

5. Enough is enough

Selective hybridization is clearly a matter of degree. Applicant demonstrably achieved selective hybridization and identification of additional clones. Of course one would verify that the clones in fact encode the protein of interest. The mere fact that Applicants have explained what every skilled artisan knows (it is possible to obtain hybridization without function) should not defeat claim 14. Applicant has in fact obtained five clones and deposited three of them. Applicants are clear that the claimed probes should include a MEF2C sequence of at least 20 bases. Obviously, longer clones will improve specificity.

B. Claim 14 contains no new matter.

The new matter rejection is a mirror image of the written description rejection, raising the same issues and reciting the same factual basis.

For all of the reasons given above, claim 14 introduces no new matter, as the original specification demonstrates possession of the invention featured in claim 14.

C. Claim 14 is enabled.

The Examiner concludes that claim 14 exceeds the breadth at which the specification enables those skilled in the art to practice the invention. The Examiner's rationale is identical to that presented above for the written description rejection,

> *As set forth in ¶4 above, the specification discloses that probes of at least 20 bases cannot selectively hybridize to nucleic acid encoding human MEF2C because not all such sequences which the probe will hybridize to will actually encode human MEF2C, i. e. the hybridization is not selective because other standard procedures for identification must be performed. Therefore, a probe that meets the limitation of selective hybridization to an encoding nucleic acid sequence has not been taught by the disclosure. The specification provides no written description, no working examples, and no specific or substantial guidance as to how the skilled artisan could routinely make and use fragments of nucleic acid comprising at least 20 contiguous bases of clone ATCC 97525 wherein said nucleic acid is able to selectively hybridize to nucleic acid encoding human MEF2C because the instant disclosure admits that such nucleic acid fragments will hybridize nonselectively to nucleic acid that does not encode human MEF2C.*

As demonstrated above, the basis for this rejection is wrong in fact (Applicant has provided working examples producing six probes) and wrong under the law. It simply is not adequate to reject a claim because it is possible that the some small percentage of the time the procedure taught in the specification will yield a result outside the scope of the claim.

The seminal case on enablement, *In re Wands,* 858 F.2d 1400, 8 USPQ2d 1217 (Fed. Cir. 1988), could not be more clear on this point. There, the claim cell fusion process rarely produced the claimed result, but the claim was enabled at a broad level because the art had no difficulty sorting the positive result from the negative result.

This case is far easier than *In re Wands*. There is no reason to believe, and the Examiner does not rest the rejection on a finding, that non-selective hybridization is likely. Applicant's own experience, documented in the specification and in deposited clones, is to the contrary. Hybridization according to the teaching in the specification yields a positive result at a high level

of certainty. The Examiner's complaint that Applicant admits to less than 100% certainty finds no support in the law or in PTO regulations or in sound policy.

(9) Appendix

The pending claims are claims 8, 11, 12 and 14. Only claim 14 is at issue in this appeal.

8. An isolated nucleic acid comprising Clone ATCC 97525.

11. An isolated nucleic acid comprising Clone ATCC 68075.

12. An isolated nucleic acid comprising Clone ATCC 75949.

14. An isolated fragment of nucleic acid comprising at least 20 contiguous bases of clone ATCC 97525, wherein said nucleic acid is able to selectively hybridize to nucleic acid encoding human MEF2C.

The brief fee of $155 is enclosed. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: 9/25/02

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